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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,438	09/05/2003	Edward J. Seppi	VM7010742001	8465

23639 7590 05/01/2006

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EXAMINER

SUCHECKI, KRYSTYNA

ART UNIT	PAPER NUMBER
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2882

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/656,438		SEPPI ET AL.	
	Examiner		Art Unit	
	Krystyna Suchecki		2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31,33-39,42-49 and 54-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-17 and 55-60 is/are allowed.
- 6) ☒ Claim(s) 18,19,22-26,29-31,33-37,42,43,45,47,49 and 54 is/are rejected.
- 7) ☒ Claim(s) 20,21,27,28,38,39,44,46 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/30/05</u> <u>3/21/06</u> <u>7/19/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 19, 22-26, 29, 30, 31, 33-37, 42 and 43 are rejected under 35

U.S.C. 102(b) as being anticipated by Brahme (EP 0 205 720 A1).

3. Regarding Claims 18, 19, 22-26, 29, 30, 31, 33-37, 42 and 43, Brahme teaches a radiation system and process comprising illuminating an object with a radiation beam at a MeV energy level; determining an image of the object formed by the radiation beam; determining radiation absorption data and configuration data using the image; and determining a treatment plan based at least in part on the determined radiation absorption data and configuration data; wherein the treatment plan is determined after the object is illuminated with the radiation beam (Abstract). A treatment beam is generated and adjusted based on the configuration data (Abstract). Adjusting comprises changing a direction of a treatment beam based upon configuration data (Pages 7-8). The beam has a constant intensity during a session (Pages 7-8). Brahme calculates radiation absorption rates in an object by studying how radiation is absorbed and then calculating attenuation coefficients (Page 4). Configuration data and absorption data are stored in a computer readable medium (Pages 5-6 and Page 10, lines 20-24). The

Art Unit: 2882

treatment plan uses a narrow pencil beam, which is a miniature computed cone, for therapy (Abstract).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 45, 47, 49 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaffray in view of (Murthy US 6,055,295).

6. Regarding Claims 45 and 49, Jaffray teaches an apparatus for irradiating an object, comprising: a platform (Figure 1) for supporting an object; a first beam source (kV) configured to generate a first radiation beam at a first intensity level and a second radiation beam (MV) at a second intensity level toward the platform; a beam adjuster (collimators or blades, Page 784) in front of the first beam source for adjusting a radiation beam directed from the first beam source; a projection detector (CCD) configured to generate a first image of the object illuminated by the first radiation beam at the first intensity level. Jaffray implies that a control module would be useful to adjust the beam adjuster so as to reduce the amount of primary intensity radiation reaching the detector plane (Page 784). Jaffray also implies the use of a multi-leaf collimator (Page 788).

7. Jaffray does not teach specifics of a control module coupled to the projection detector and to the beam adjuster, wherein the control module is configured to adjust

Art Unit: 2882

one or a combination of a shape, an intensity, and a direction of the second radiation beam. Nor does Jaffray teach the beam adjuster of the first radiation beam expressly to be a multi-leaf collimator.

8. However, Murthy teaches an imaging system where a multi-leaf collimator (Column 3, lines 1-2) is connected to a detector so as to reduce the amount of primary intensity radiation reaching a detector plane (Abstract). By conforming to body and non-body regions, the control module attached to the multi-leaf collimator adjusts at least the shape of the radiation beam. This system also reduces scattered radiation and improves image quality (Columns 1-2).

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the multi-leaf collimator and shape-changing control module as taught by Murthy in the device of Jaffray in order to accomplish the goal of reducing the amount of primary intensity radiation reaching the detector plane (Jaffray, Page 784) while also reducing scattered radiation and improving image quality (Murthy, Columns 1-2).

10. Regarding Claims 47 and 54, Jaffray discusses that it would be advantageous to include a treatment planning system in to the imaging system afforded by the kV and MV sources.

11. Jaffray does not expressly a control module as configured to develop a radiation treatment plan based on the first image or based on one or both of the first image and the second image.

Art Unit: 2882

12. However, Jaffray teaches that including a treatment planning system would enable the combination of dose planning, and machine and imaging control in an integrated environment. The combination would significantly alter clinical approaches (Page 787).

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a control module configured to develop a radiation treatment plan based on the first image or based on one or both of the first image and the second image in the system of Jaffray, as suggested, in order to combine dose planning, and machine and imaging control in an integrated environment in order to significantly alter clinical approaches (Jaffray, Page 787).

Allowable Subject Matter

14. Claims 1-17 and 55-60 are allowed.

15. Claims 20, 21, 27, 28, 38, 39, 44, 46 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: claims 1 and 14 contain allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest a radiation method or system comprising illuminating an object with a first beam at a first energy level, determining a first image of an object formed by the first beam, determining configuration data using the first image, illuminating the object with a second beam at a second energy level, determining a second image of the object formed by the second beam, determining

Art Unit: 2882

radiation absorption data using the second image, and determining a radiation treatment plan using the configuration data and the radiation absorption data wherein the radiation plan is determining before or during a treatment session as claimed.

Though dual energy systems are per se known in the art (see Swerdloff, as cited by Applicant), images are not typically made from both energies. Furthermore, data regarding absorption and configuration are not usually obtained from beams of separate energies as claimed.

17. Claims 20 and 27 contains allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest a radiation method or system comprising illuminating an object with a beam at a MeV energy level, determining an image of the object, determining configuration and absorption data and determining a radiation treatment plan based on the datum further comprising adjusting an intensity of the beam during a session as claimed.

18. Claims 21 and 28 contain allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest a radiation method or system comprising illuminating an object with a beam at a MeV energy level, determining an image of the object, determining configuration and absorption data and determining a radiation treatment plan based on the datum further comprising comparing data associated with the image with data regarding configuration of the object specified in a treatment prescription, as claimed.

19. Claims 38 and 44 contain allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest a radiation method or system

Art Unit: 2882

comprising illuminating an object with a beam at a MeV energy level, determining an image of the object, determining configuration and absorption data and determining a radiation treatment plan based on the datum further comprising gating delivery of radiation based on the configuration data as claimed.

20. Claim 39 contains allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest a radiation method or system comprising illuminating an object with a beam at a MeV energy level, determining an image of the object, determining configuration and absorption data and determining a radiation treatment plan based on the datum further comprising verifying a treatment plan before illuminating an object with a treatment beam.

21. Claims 46 contains allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest an apparatus for irradiating an object comprising a platform, a first beam source generating a first radiation beam at a first intensity level and a second radiation beam at a second intensity level, a beam adjuster in front of the first beam source, a projection detector, and a control module wherein the projection detector generates images of the object form illumination by both the first and second radiation beams as claimed. Claim 48 contains allowable subject matter at least by virtue of its dependency.

Response to Arguments

22. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


Art Unit: 2882

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krystyna Suchecki whose telephone number is (571) 272-2495. The examiner can normally be reached on M-F, 9-5.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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